PATENT
Attorney Docket No. 01035.0033-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
John F. BOYLAN et al.	)	Group Art Unit: 3731
	)	
Application No.: 10/764,841	)	Examiner: Ryan J. Severson
	)	
Filed: January 26, 2004	)	Confirmation No.: 9783
	)	
For: NITINOL ALLOY DESIGN FOR SHEATH DEPOLYABLE AND RE-SHEATHABLE VASCULAR DEVICES	)	**Mail Stop AF**

Attention: Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF UNDER BOARD RULE § 41.37

In support of the Notice of Appeal filed on April 30, 2008, and further to Board Rule 41.37, Appellants present this brief and enclose herewith the fee of $510.00 required under 37 C.F.R. § 1.17(c).

The time period for filing an appeal brief was reset to be one-month from the mailing date of the Notice of Panel Decision from Pre-Appeal Brief Review mailed on July 22, 2008. Accordingly, this Appeal Brief is timely filed with the enclosed Petition and fee for a one month extension of time.

This Appeal responds to the October 31, 2007, Final Office Action ("Final Office Action") that maintained the rejection of claims 1, 2-6 and 15-20.

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Real Party In Interest

Abbott Cardiovascular Systems Inc. is the real party in interest, as evidenced by the assignment recorded in the U.S. Patent Office at Reel No. 019235, Frame No. 0557 on April 25, 2007.

Related Appeals and Interferences

There are currently no other appeals or interferences, of which Appellants, Appellants' legal representative, or Assignee are aware, that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claims 1-6 and 15-20 are pending. Claims 7-14 have been cancelled. Claims 1, 2-6 and 15-20 stand rejected and are appealed. No claims have been allowed.

In accordance with 37 C.F.R. § 41.37(c)(1)(viii), the attached Appendix contains a clean copy of the pending claims.

Status of Amendments

No claim amendments have been made in response to or subsequent to the final Office Action dated October 31, 2007.

Summary of Claimed Subject Matter

The present invention relates generally to filtering devices and systems which can be used when an interventional procedure is being performed in a stenosed or occluded region of a blood vessel to capture embolic material that may be created and released into the bloodstream during the procedure. Appellants' specification, paragraph [0002]. In one embodiment, which is recited in **independent claim 1**, the invention relates to an embolic filtering system for use in a body lumen, comprising a self-expanding strut assembly including a superelastic alloy, wherein the superelastic alloy comprises at least one ternary element and exhibits a decreased stress hysteresis due to a lowered loading plateau stress compared to that of the superelastic alloy without the at least one ternary element, and a filter element disposed on the strut assembly. *See* Appellants' specification at paragraph [00020], page 6, lines 18-26, at paragraph [00021], page 6, line 27 to page 7, line 2, and at paragraphs [00022]-[00026], page 7, line 3 to page 8, line 4.

In another embodiment, which is recited in **independent claim 20**, the invention relates to an embolic filtering system for use in a body lumen, comprising a self-expanding strut assembly including a superelastic alloy, wherein the superelastic alloy comprises at least one ternary element and exhibits a decreased stress hysteresis due to a lowered loading plateau stress compared to that of the superelastic alloy without the at least one ternary element, wherein the superelastic alloy comprises about 30 to about 52 atomic percent of titanium, the balance of nickel, and up to about 15 atomic percent of the at least one ternary element selected from the group consisting of palladium, platinum, tantalum, and alloys thereof, and a filter element disposed on the

strut assembly. *See* Appellants' specification at paragraph [00020], page 6, lines 18-26, at paragraph [00021], page 6, line 27 to page 7, line 2, at paragraphs [00022]-[00026], page 7, line 3 to page 8, line 4, and at paragraph [00077], page 19, lines 9-16.

Grounds of Rejection

A. Claims 1, 2, 4, 6 and 15-20 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,910,154 to Tsugita et al. ("Tsugita") in view of U.S. Patent No. 5,885,381 to Mitose et al. ("Mitose").

B. Claims 3 and 5 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Tsugita in view of Mitose and further in view of U.S. Patent No. 5,713,853 to Clark et al. ("Clark").

Argument

Each claim of the present application is separately patentable, and upon issuance of a patent will be entitled to a separate presumption of validity under 35 U.S.C. § 282. The arguments set forth below are arranged under subheadings, and in accordance with 37 C.F.R. § 41.37(c)(1)(vii), these subheadings indicate the claims whose patentability is argued separately.

A. Rejection of Claims 1, 2, 4, 6 and 15-20 under 35 U.S.C. § 103(a) over Tsugita in view of Mitose

Claims 1, 2, 4, 6 and 15-20 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,910,154 to Tsugita et al. ("Tsugita") in view of U.S. Patent No. 5,885,381 to Mitose et al. ("Mitose"). Office Action dated October 31, 2007 at pp. 2-3. The Examiner asserts that Tsugita "discloses the invention substantially as claimed, including a 'self-expending strut assembly' (54) including a nickel-titanium alloy'" (citing col. 8, lines 48-50) and "a 'filter element' (60) disposed on the strut assembly'" (citing Figures 6A and 6B). *Id.* at p. 2. However, the Examiner admits that Tsugita "does not disclose the superelastic alloy includes a ternary element." *Id.* To remedy this deficiency, the Examiner relies on Mitose. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to replace the nickel-titanium strut assembly of Tsugita reference with the alloy of Mitose having a ternary element (palladium) to reduce the stress hysteresis and improve hot workability in the device. *Id.* at p. 3. Appellants respectfully disagree and traverse this rejection for at least the following reasons.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. M.P.E.P. § 2142. In *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q. 2d 1385 (2007), the Supreme Court confirmed that the "framework for applying the statutory language of §103" was still based on its landmark decision in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). As detailed below, it is evident that the Examiner has not established a *prima facie* case of obviousness even in light of the *KSR* decision. Specifically, the Examiner has failed to show that the alloys disclosed in the cited references exhibits a decreased stress hysteresis **due to a lowered loading plateau stress**, as claimed. In fact the Examiner cannot show this because the references, namely Mitose, desire just the opposite.

Hysteresis is defined by the difference between the loading and unloading plateau stresses of the material as plotted on a stress-strain curve. To illustrate the difference of the present invention in comparison with Mitose, as discussed above, Appellants submit the following three figures. Figure 1 represents a typical stress-strain hysteresis. Figure 2 represents the mechanism by which Mitose achieves a smaller hysteresis. As discussed in Mitose at col. 5, lines 25-28, and as indicated by the upward arrow, a smaller hysteresis is a result of a higher unloading plateau stress. Figure 3 is an illustrative superelastic stress-strain curve according to the present invention in comparison with the standard superelastic NiTi. This Figure shows a downward arrow indicating a smaller hysteresis is a result of a lower loading plateau stress.

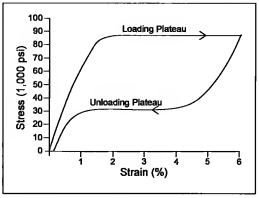

Figure 1: Typical Stress-Strain curve for superelastic NiTi.

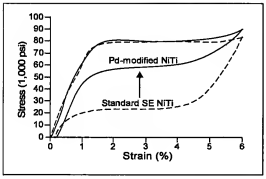

Figure 2: Superelastic stress-strain curve described in Mitose.

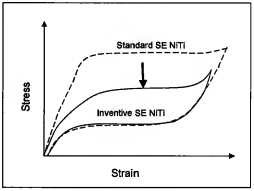

Figure 3: Illustrative superelastic stress-strain curve according to the present invention.

The graphical representation mentioned above is not only taught in Mitose, but it is specifically exemplified. As shown, in col. 7, lines 35-40, the inventive alloys of Mitose (1-8) achieved desired properties over the closest comparative examples 9 and 10, which contain Pd, like Examples 1-8, by increasing the unloading stress.

Thus, even if the intent of Mitose (to achieve a lower stress hysteresis by adding a ternary element) is the same as the claimed invention, the means by which it is achieved is completely opposite to the claimed invention. Therefore, the Examiner has failed to show that the alloy of Tsugita, alone or in view of Mitose, achieves a decreased stress hysteresis by **decreasing the loading plateau stress**, as claimed.

The Examiner relies on Figs. 2 and 4 of Mitose to allegedly show that "the plateau stress is lower in the alloy having the ternary element (well below 400 MPa) than the alloy without the ternary element (at or above 400 MPa)." *Id.* at 5. This comparison is improper for at least the reason that Figs. 1-3 of Mitose represent "prior art" and not comparative examples conducted by Mitose. As such, the figures do not support the Examiner's conclusion that "the reduction of the stress hysteresis as taught by Mitose . . . is at least in part due to the reduction in the loading plateau." *Id.* The Examiner is simply comparing apples and oranges.

Furthermore, contrary to the Examiner's positions, to the extent that Mitose ever explicitly describes the intent of the loading and unloading stress in his inventive alloys, it is to achieve as high of a loading stress as possible. *See, e.g.,* col. 5, lines 22-32 ("[w]hen the superelastic alloy material is used for the orthodontic archwire, it is desired that a certain amount of tensile force should be applied in working **(loading)** to attach the wire to the teeth, and that a tensile force **should be as high as possible** in unloading to move the teeth after attaching the wire to the teeth, namely, the stress hysteresis should be small."). (Emphasis added) *See also,* col. 10, lines 1-7.

In order to satisfy the initial burden of establishing a *prima facie* case of obviousness, the Examiner first must show that the prior art references teach or suggest all the claim limitations. *See In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). The Examiner must also show that there is some suggestion or motivation, either in the references or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references. *In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998).

Nothing in either Tsugita or Mitose teaches obtaining a decreased stress hysteresis by decreasing the loading plateau stress, as claimed. In fact, this rejection is fatally flawed since it relies on a reference, Mitose, that clearly teaches away from the claimed invention. *See In re Laskowski,* 10 USPQ 2d 1397 (Fed. Cir. 1989). For this reason alone, Appellants respectfully request this rejection be withdrawn.

Additionally, even if the Examiner has established that the claimed invention is obvious, which he has not, an Appellant can rebut a *prima facie* case of obviousness by presenting comparative test data showing that the claimed invention possesses unexpectedly improved properties or properties that the prior art does not have. *See* M.P.E.P. § 716.02(a). Accordingly, in order to advance prosecution, Appellants submitted an article with the Reply filed August 15, 2007, titled, "The Development of Radiopaque Nitinol," written by John F. Boylan ("the Boylan article"), one of the inventors of the present application. This document is available in the Image File Wrapper (IFW). Appellants submit that this article provides evidence that establishes that the claimed embolic filter system comprising a strut assembly which includes a nickel-titanium alloy and a ternary element, as recited in claim 1 for example, is unexpectedly superior as compared with the Nitinol struts disclosed in Tsugita.

Nitinol has many attractive properties which makes it useful for human implant application. *See* Boylan article at page 2. Nitinol's superelastic mechanical properties are outstanding for the demanding kinetic environment experienced by vascular stents. *See id.* Moreover, the supple responsiveness of superelastic Nitinol allows a stent to recover from compressive or impact loads in superficial arteries, for example the carotid

artery. *See id.* However, both nickel and titanium, and therefore Nitinol, have intrinsically poor radiopacity. *See id.*

In an effort to improve the radiopacity of Nitinol while still retaining its superelastic properties, Boylan investigated adding a ternary element to a nickel-titanium alloy. Surprisingly, as shown in Fig. 3, Boylan found that a nickel-titanium-palladium and a nickel-titanium-platinum alloy are radiopaque and exhibit improved superelastic properties as compared to Nitinol, which is the material used in the strut assembly in Tsugita. *See id.* at page 4. Moreover, as shown in Fig. 6, the nickel-titanium-platinum alloy has exceptionally superior superelastic properties over that of conventional binary Nitinol. *See id.* at page 6. Most notably and advantageously, Boylan found that the ternary alloy has significantly less mechanical hysteresis than that of binary Nitinol. *See id.* at page 4. Less difference between the upper plateau stress, or loading stress, and the lower plateau stress, or unloading stress, means that, for example, once a stent has been designed to provide a desired outward force upon an implant (the unloading stress), the forces to collapse and contain the stent in the delivery system is significantly reduced. *See id.* A reduced collapsing force means a lighter, more flexible delivery system. *Id.* Thus, based on the results discussed in the Boylan article, it is clear that a strut assembly of the claimed invention which includes a nickel-titanium alloy and a ternary element has unexpectedly improved superelastic properties as compared to Nitinol struts disclosed in Tsugita.

For at least the foregoing reasons, Appellants submit that the Examiner has failed to establish a *prima facie* case of obviousness over Tsugita and Mitose. Even if the Examiner had established that the claimed invention is obvious, which he did not,

Appellants have presented sufficient evidence to rebut any *prima facie* showing. Accordingly, Appellants respectfully request that this rejection be withdrawn.

B. Rejection of Claims 3 and 5 under 35 U.S.C. §103(a) over Tsugita in view Mitose and further in view of Clark

Claims 3 and 5 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Tsugita in view of Mitose and further in view of U.S. Patent No. 5,713,853 to Clark et al. ("Clark"). Office Action dated October 31, 2007 at p. 4. Appellants respectfully disagree and traverse this rejection for at least the following reasons.

As discussed in Section A above, the Examiner has failed to show that Tsugita or Mitose provide any reason why one of ordinary skill in the art would have combined the elements in the manner claimed. Clark does not remedy the deficiencies of Tsugita and Mitose. In fact, the Examiner relies on Clark to support the assertion that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to shape the strut members with the diamond shape pattern . . . by laser cutting." Office Action at 4. However, with respect to the deficiencies in the primary references mentioned above, Clark is not concerned with superelastic materials it never mentions a stress hysteresis, and certainly does not teach how to reduce a stress hysteresis, as claimed. Thus, this combination of references does not establish a *prima facie* case of obviousness of claims 3 and 5. Accordingly, Appellants respectfully request that this rejection be withdrawn.

Conclusion

For the reasons given above, pending claims 1-6 and 15-20 are allowable and withdrawal of each of the Examiner's rejection is respectfully requested.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: August 26, 2008

By 
Jennifer R. Leach
Reg. No. 54,257

Claims Appendix to Appeal Brief Under Rule 41.37(c)(1)(viii)

1. (previously presented) An embolic filtering system for use in a body lumen, comprising

a self-expanding strut assembly including a superelastic alloy, wherein the superelastic alloy comprises at least one ternary element and exhibits a decreased stress hysteresis due to a lowered loading plateau stress compared to that of the superelastic alloy without the at least one ternary element; and

a filter element disposed on the strut assembly.

2. (original) The embolic filtering system of claim 1, wherein the system includes an elastic sheath at least partially overlying the filter element.

3. (original) The embolic filtering system of claim 2, wherein the self-expanding strut assembly is cut from a tube with truncated diamond shape openings.

4. (original) The embolic filtering system of claim 1, wherein the self-expanding strut assembly when deployed has a generally conical shape with a first base, and the filter element when deployed has a generally conical shape with a second base, and wherein the first and second bases are joined.

5. (original) The embolic filtering system of claim 1, wherein the self-expending strut assembly includes a strut pattern that is laser cut from a tube.

6. (original) The embolic filtering system of claim 1, wherein the alloy includes a transition temperature set below human body temperature.

7-14. (canceled).

15. (previously presented) The filtering system of claim 1, wherein the self-expanding strut assembly expands inside the body lumen through shape memory effect.

16. (previously presented) The filtering system of claim 1, wherein the superelastic alloy includes a transition temperature below 45 degrees C.

17. (previously presented) The filtering system of claim 1, wherein the superelastic alloy comprises about 30 to about 52 atomic percent of titanium, the balance of nickel, and up to about 15 atomic percent of the at least one ternary element.

18. (previously presented) The filtering system of claim 1, wherein the at least one ternary element is selected from the group consisting of palladium, platinum, chromium, iron, cobalt, vanadium, manganese, boron, copper, aluminum, tungsten, tantalum, zirconium, and alloys thereof.

19. (previously presented) The filtering system of claim 18, wherein the at least one ternary element is selected from the group consisting of palladium, platinum, tantalum, and alloys thereof.

20. (previously presented) An embolic filtering system for use in a body lumen, comprising

a self-expanding strut assembly including a superelastic alloy, wherein the superelastic alloy comprises at least one ternary element and exhibits a decreased stress hysteresis due to a lowered loading plateau stress compared to that of the superelastic alloy without the at least one ternary element;

wherein the superelastic alloy comprises about 30 to about 52 atomic percent of titanium, the balance of nickel, and up to about 15 atomic percent of the at

least one ternary element selected from the group consisting of palladium, platinum, tantalum, and alloys thereof; and

a filter element disposed on the strut assembly.

Evidence Appendix to Appeal Brief Under Rule 41.37(c)(1)(ix)

No evidence is being relied upon by Appellants in this appeal.

Related Proceedings Appendix to Appeal Brief Under Rule 41.37(c)(1)(x)

No related proceedings.